

The Examiner states that Dattagupta "describes compositions and methods for releasing nucleic acids from cells in a form that is suitable for labeling/capture, amplification, or detection in a single reagent addition step" and which include "a lipid, membrane fluidizing compound, enzyme for degrading cell structure, metal chelators, or one or more nucleic acid probes or primers complementary to the nucleic acid to be detected." Office Action at page 3, lines 1-5.

Applicant respectfully traverses the rejection. For a reference to anticipate the claimed invention under 35 U.S.C. § 102, the reference must describe the invention such that "each and every limitation is found either expressly or inherently" within it. *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370, 62 USPQ2d 1865, 1869 (Fed. Cir. 2002) (citations omitted); see Manual of Patent Examining Procedure § 2131 (8th ed. 2001) ("MPEP") ("to anticipate a claim, the reference must teach every element of the claim").

Claim 1 of the present application recites a composition for releasing nucleic acids from a biological sample that comprises at least one cationic surfactant, at least one protease, and a buffer. Claims 2-16 and 20-25 all ultimately depend from claim 1.

At the outset, Applicant notes that the Examiner failed to cite a particular section of Dattagupta that she considered to teach a composition for releasing nucleic acids from a sample comprising a cationic surfactant.

From the undersigned's review, however, Dattagupta discusses cationic surfactants as only being useful in liposome preparations for the "removal of surfactant approach." Dattagupta, column 6, lines 57-65. In that approach, the cationic surfactants must be removed by filtration or dialysis. *Id.* In fact, the cationic surfactant

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is removed from the solution before the composition of Dattagupta is exposed to a biological sample. *Id.*, col. 6, lines 64-65. Thus, Dattagupta does not teach a composition for releasing nucleic acids from a biological sample comprising a cationic surfactant. Accordingly, the Examiner fails to establish that Dattagupta anticipates claims 1-16 and 20-25.

For at least the reason presented above, the Examiner has failed to establish that Dattagupta would have anticipated claims 1-16 and 20-25. Thus, Applicant need not address the Examiner's contentions concerning other limitations of those claims at pages 2-6 of the Action. By not addressing those contentions, Applicant in no way acquiesces to those contentions.

Reconsideration and withdrawal of the §102 rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-25 under 35 U.S.C. § 103(a) as allegedly being obvious over Dattagupta in view of U.S. Pat. No. 5,130,423 to Van Ness et al. ("Van Ness"). Office Action, pages 6 to 8, Item No. 5.

The Examiner states that Dattagupta teaches the use of "compositions include[ing] a lipid, membrane fluidizing compound, enzyme for degrading cell structure, metal chelators, or one or more nucleic acid probes or primers complementary to the nucleic acid to be detected." Action, page 6, Item No. 5. The Examiner alleges that "it would have been obvious at the time the invention was [made] to [include a nuclease] inhibitor such as bentonite as taught by Van Ness for the method of Dattagupta." *Id.*, at page 7, lines 9-10. The Examiner further alleges that the motivation for the use of the nuclease inhibitor is to avoid the use of phenol or phenol/chloroform, thereby avoiding

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"hazardous waste" and a "time consuming and laborious" process. *Id.*, at page 7, lines 14-16. Applicant respectfully traverses the rejection.

As discussed above, Claim 1 recites in part a composition for releasing nucleic acids from a biological sample comprising a cationic surfactant. All of the dependent claims 2-25 ultimately depend from claim 1, and thus include all of the limitations of claim 1. As discussed above, the Examiner fails to establish, that Dattagupta teaches a composition for releasing nucleic acids comprising a cationic surfactant. Moreover, the Examiner fails to assert, let alone establish that Dattagupta would have suggested such a composition. Further, Van Ness does not teach and would not have suggested a composition for releasing nucleic acids comprising a cationic surfactant.

Thus, the Examiner has failed to establish that the combination of Dattagupta and Van Ness would have rendered obvious any of the rejected claims. Moreover, applicant need not address the Examiner's contentions concerning the combination of Dattagupta and Van Ness with respect to other limitations of certain dependent claims. By not addressing those contentions, Applicant in no way acquiesces to those contentions.

Applicant respectfully requests reconsideration and withdrawal of the § 103 rejections of claims 1-25 in view of Dattagupta and Van Ness.

Conclusion

Applicant respectfully asserts that the application is in condition for allowance. If the Examiner does not consider the application to be in condition for allowance, Applicant requests that the Examiner call the undersigned (650 849-6676) to arrange an interview prior to taking action.

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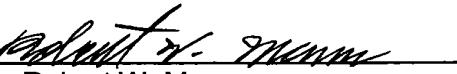
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Please grant any extensions of time required to enter this response and charge
any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: August 30, 2002

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